

Paper No. _____

Filed on behalf of Akorn Inc.

By: Michael R. Dzwonczyk

Azy S. Kokabi

Travis Ribar

Sughrue Mion, PLLC

2100 Pennsylvania Ave., NW

Washington, DC 20037

Telephone: 202-293-7060

Facsimile: 202-293-7860

email: mdzwonczyk@sughrue.com

akokabi@sughrue.com

tribar@sughrue.com

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AKORN INC.

Petitioner

v.

ALLERGAN, INC.

Patent Owner

Case No. IPR2017-00601

Patent No. 9,248,191

**PETITION FOR INTER PARTES REVIEW OF
U.S. PATENT NO. 9,248,191**

TABLE OF CONTENTS

	<u>Page</u>
I. Introduction.....	1
A. Brief Overview of the '191 Patent	3
B. Brief Overview of the Prosecution History.....	4
C. Brief Overview of the Scope and Content of the Prior Art.....	8
i. U.S. Patent No. 5,474,979 to Ding <i>et al.</i> (“Ding ’979,” EX1006).....	8
ii. Sall <i>et al.</i> , <i>Two Multicenter, Randomized Studies of the Efficacy and Safety of Cyclosporine Ophthalmic Emulsion in Moderate to Severe Dry Eye Disease</i> , 107 OPTH. 631 (2000) (“Sall” EX1007).....	9
iii. A. Acheampong <i>et al.</i> , <i>Cyclosporine Distribution into the Conjunctiva, Cornea, Lacrimal Gland, and Systemic Blood following Topical Dosing of Cyclosporine to Rabbit, Dog, and Human Eyes</i> , 2 LACRIMAL GLAND, TEAR FILM, AND DRY EYE SYNDROMES 1001 (1998) (“Acheampong,” EX1008).....	10
iv. U.S. Patent No. 5,578,586 to Glonek <i>et al.</i> (“Glonek,” EX1009).....	11
D. Brief Overview of the Level of Skill in the Art	11
II. Grounds For Standing.....	13
III. Mandatory Notices Under 37 C.F.R. § 42.8.....	13
IV. Statement Of The Precise Relief Requested.....	15
V. Statement Of Non-Redundancy.....	15
VI. Claim Construction.....	16
A. “buffer”	17

B.	“substantially no detectable concentration”	17
C.	“effective,” “lacrimonal gland tearing,” “overall efficacy substantially equal to,” “as much therapeutic efficacy as”	18
D.	“demonstrates a reduction in adverse events”	20
E.	“breaks down”	20
VII.	Background Knowledge in the Art Prior to September 15, 2003	21
VIII.	Detailed Explanation of Grounds for Unpatentability	27
A.	[Ground 1] Claims 1-16 and 21-27 are Obvious under 35 U.S.C. § 103 over Ding ’979 and Sall	27
i.	Claims 1-16	31
ii.	Claims 21-27	41
B.	[Ground 2] Claims 1-16 and 21-27 are Obvious under 35 U.S.C. § 103 over Ding ’979, Sall, and Acheampong	50
C.	[Ground 3] Claims 17-20 are Obvious under 35 U.S.C. § 103 over Ding ’979, Sall, and Glonek	52
D.	[Ground 4] Claim 20 is Obvious under 35 U.S.C. § 103 over Ding ’979, Sall, Glonek, and Acheampong.	56
IX.	No Objective Indicia of Non-Obviousness: No Unexpected Results	57
X.	Conclusion	69
XI.	Certificate Of Compliance	71
XII.	Payment Of Fees Under 37 C.F.R. §§ 42.15(A) AND 42.103	72
XIII.	Appendix – List Of Exhibits	73

I. INTRODUCTION

On December 8, 2016, the Board instituted IPR2016-01132, stating that there was a reasonable likelihood that claims 1-27 of U.S. Patent No. 9,248,191 to Acheampong *et al.* (“the ’191 patent,” EX1001) are unpatentable as obvious. *Mylan Pharm., Inc. v. Allergan, Inc.*, IPR2016-01132, slip op. at 24 (PTAB December 8, 2016) (Paper 8). The present Petition presents the same grounds of unpatentability and the same arguments and evidence as the Petition in IPR2016-01132. The present Petitioner has received permission from Mylan Pharmaceuticals, Inc., the petitioner in IPR2016-01132, to rely upon the same expert. The present Petition is substantially identical to the Petition filed in IPR2016-01132. Accordingly, it is believed that the present Petition should be granted for the same reasons that the Board instituted IPR2016-01132.

In particular, Akorn Inc. (“Petitioner”) requests review of the ’191 patent that issued on February 2, 2016. PTO records indicate the ’191 patent is assigned to Allergan, Inc. (“Patent Owner”). This Petition demonstrates that there is a reasonable likelihood that claims 1-27 of the ’191 patent are unpatentable for failing to distinguish over prior art. Additional petitions are being filed to address related patents that are assigned to Patent Owner. All challenged patents are continuations from the same family and are terminally disclaimed over one

another. The patents claim an ophthalmic emulsion for the treatment of overlapping ocular disorders, or conventional methods of administering the emulsion.

The '191 patent claims concern conventional methods of treating dry eye disease, such as keratoconjunctivitis sicca (“KCS”) by the “twice a day” topical ophthalmic administration of an emulsion containing cyclosporin A (“CsA”), castor oil, and other standard ingredients, as generally claimed in related U.S. Patent No. 8,685,930. Each element of the emulsion, including the claimed CsA and castor oil percentages and methods for administering them to treat dry eye disease/KCS, were disclosed in a single prior art reference (Ding '979) for use in topical ophthalmic emulsions to enhance and restore lacrimal gland tear production and treat dry eye disease. During prosecution of a parent application, applicants admitted the claimed emulsion containing 0.05% CsA / 1.25% castor oil “is squarely within the teaching of the Ding [’979] reference” and “would have been obvious” to a person of skill in the art at the time of the invention. EX1005, 0435; EX1002, ¶20. A second 102(b) prior art reference, Sall, discloses twice-daily administration of a 0.05% CsA-in-castor oil emulsion for the same purpose.

In prosecuting a continuation application, applicants changed course and attempted to withdraw the admissions regarding Ding '979, arguing that data

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.